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PTO/SB/21 (03-03)

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**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

Application Number	10/773,083
Filing Date	02/04/2004
First Named Inventor	Daniel J. CUA
Art Unit	1615
Examiner Name	
Attorney Docket Number	DX06023 US 01

Total Number of Pages in This Submission

9

**ENCLOSURES (Check all that apply)**

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to Group
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Request for Refund	
<input checked="" type="checkbox"/> Information Disclosure Statement (2 pages)	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<b>Other Enclosures/Remarks:</b>	
<input type="checkbox"/> Response to Missing Parts/Incomplete Application	<ul style="list-style-type: none"><li>• Form PTO/SB/08 (6 pages)</li><li>• Return Receipt Postcard</li></ul>	
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm or Individual	Sheela Mohan-Peterson, Reg. No. 41,201 DNAX Research, Inc. 901 California Ave. Palo Alto, CA 94304-1104
Signature	
Date	28-July-2004

**CERTIFICATE OF TRANSMISSION/MAILING**

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Typed or printed	MELANIE LYONS		
Signature		Date	7-28-04

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Attorney Docket: DX06023US01

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Re application of:

Daniel J. CUA, et al.

Application No.: 10/773,083

Filed: 02/04/2004

For: **USES OF MAMMALIAN  
CYTOKINE; RELATED  
REAGENTS**

Examiner: Unknown

Art Unit: 1615

Conf. No.: 3286

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

by:

  
MELANIE LYONS

**INFORMATION DISCLOSURE STATEMENT**

Sir:

The materials as listed in the attached form PTO/SB/08 are brought to the Examiner's attention pursuant to the duty of disclosure under 37 C.F.R. § 1.56, § 1.97, and § 1.98.

Citation of these documents should not be construed as a representation that the documents are in fact material or are in fact prior art with respect to the instant invention. The Examiner should not make any inference relating to the relative pertinence of cited references based upon the order in which the art is presented. Citation of these documents should not be construed as a representation that a search has been made or that more pertinent art may not be in existence.

Applicants request that the Examiner fully consider the art cited in the attached PTO/SB/08 form. Applicants further request that the Patent and Trademark Office list all such art on the front of any patent issuing from this application.

Applicants believe no fee is required for filing this document; however, if such a fee is required, the Commissioner is hereby authorized to charge DNAX Research Institute Deposit account no. 04-1239.

Respectfully submitted,

Date: 28-July-2004

By: Sheela Mohan-Peterson  
Sheela Mohan-Peterson, Reg. No.  
41,201  
Attorney for Applicants

**Customer No. 28008**  
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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

1

of

6

**Complete if Known**

Application Number	10/773,083
Filing Date	02/04/2004
First Named Inventor	Daniel J. CUA
Art Unit	1615
Examiner Name	
Attorney Docket Number	DX06023US01

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	DOCUMENT NUMBER	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant, Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant, Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AA	Andoh, <i>et al.</i> (2002) <i>Int. J. Mol. Med.</i> 10:631-634 "Interleukin (IL)-4 and IL-17 Synergistically Stimulate IL-6 Secretion in Human Colonic Myofibroblasts"	
	AB	Annacker, <i>et al.</i> (2001) <i>J. Immunol.</i> 166:3008-3018 "CD25 <sup>+</sup> CD4 <sup>+</sup> T Cells Regulate the Expansion of Peripheral CD4 T Cells Through the Production of IL-10 <sup>11</sup> "	
	AC	Atreya, <i>et al.</i> (2000) <i>Nature Med.</i> 6:583-588 "Blockade of interleukin 6 <i>trans</i> signaling suppresses T-cell resistance against apoptosis in chronic intestinal inflammation: Evidence in Crohn disease and experimental colitis <i>in vivo</i> "	
	AD	Berg, <i>et al.</i> (1996) <i>J. Clin. Invest.</i> 98:1010-1012 "Enterocolitis and Colon Cancer in Interleukin-10-deficient Mice Are Associated with Aberrant Cytokine Production and CD4 <sup>+</sup> TH1-like Responses"	
	AE	Bhan, <i>et al.</i> (1999) <i>Immunol. Rev.</i> 169:195-207 "Colitis in transgenic and knockout animals as models of human inflammatory bowel disease"	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.<sup>1</sup> Applicant's unique citation designation number (optional).<sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).<sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.<sup>6</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/773,083
				Filing Date	02/04/2004
				First Named Inventor	Daniel J. CUA
				Art Unit	1615
				Examiner Name	
Sheet	2	of	6	Attorney Docket Number	DX06023US01

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AF	Boddeke (2001) <i>Euro. J. Pharmacol.</i> 429:115-119 "Involvement of chemokines in pain"	
	AG	Bouma and Strober (2003) <i>Nat. Rev. Immunol.</i> 3:521-533 "The Immunological and Genetic Basis of Inflammatory Bowel Disease"	
	AH	Calcutt (2002) <i>Int. Rev. Neurobiol.</i> 50:205-228 "Potential Mechanisms of Neuropathic Pain in Diabetes"	
	AI	Chu, <i>et al.</i> (2000) <i>J. Exp. Med.</i> 192:123-128 "Failure to Suppress the Expansion of the Activated CD4 T Cell Population in Interferon $\gamma$ -deficient Mice Leads to Exacerbation of Experimental Autoimmune Encephalomyelitis"	
	AJ	Cua, <i>et al.</i> (2003) <i>Nature</i> 421:744-748 "Interleukin-23 rather than interleukin-12 is the critical cytokine for autoimmune inflammation of the brain"	
	AK	Davidson, <i>et al.</i> (1998) <i>J. Immunol.</i> 161:3143-3149 "IL-12, But Not IFN- $\gamma$ , Plays a Major Role in Sustaining the Chronic Phase of Colitis in IL-10-Deficient Mice"	
	AL	Davidson, <i>et al.</i> (1996) <i>J. Exp. Med.</i> 184:241-251 "T Helper Cell 1-type CD4 <sup>+</sup> T Cells, but Not B Cells, Mediate Colitis in Interleukin 10-deficient Mice"	
	AM	Elkins, <i>et al.</i> (2002) <i>Infection Immunity</i> 70:1936-1948 "In Vivo Clearance of an Intracellular Bacterium, <i>Francisella tularensis</i> LVS, Is Dependent on the p40 Subunit of Interleukin-12 (IL-12) but Not on IL-12 p70"	
	AN	Fossiez (1998) <i>Int. Rev. Immunol.</i> 16:541-551 "Interleukin-17"	
	AO	Frucht (2002) <i>Sci STKE</i> 2002, E1-E3 "IL-23: A Cytokine That Acts on Memory T Cells"	
	AP	Fujino, <i>et al.</i> (2003) <i>Gut</i> 52:65-70 "Increased expression of interleukin 17 in inflammatory bowel disease"	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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				First Named Inventor	Daniel J. CUA
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Sheet	3	of	6	Attorney Docket Number	DX06023US01

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AQ	Green (2003) <i>The Lancet</i> 362:383-391 "Coeliac disease"	
	AR	Griffin and Mrak (2002) <i>J. Leukocyte Biol.</i> 72:233-238 "Interleukin-1 in the genesis and progression of and risk for development of neuronal degeneration in Alzheimer's disease"	
	AS	Gross, <i>et al.</i> (1992) <i>Gastroenterol.</i> 102:514-519 "Evidence for Continuous Stimulation of Interleukin-6 Production in Crohn's Disease"	
	AT	Hanauer (1996) <i>New Engl. J. Med.</i> 334:841-848 "Inflammatory Bowel Disease"	
	AU	Hata, <i>et al.</i> (2002) <i>Am. J. Physiol. Gastrointest. Liver Physiol.</i> 282:G1035-G1044 "IL-17 stimulates inflammatory responses via NF- $\kappa$ B and MAP kinase pathways in human colonic myofibroblasts"	
	AV	Hickey, <i>et al.</i> (1991) <i>J. Neurosci. Res.</i> 28, 254-60 "T-Lymphocyte Entry Into the Central Nervous System"	
	AW	Hoozemans, <i>et al.</i> (2001) <i>Exp. Gerontol.</i> 36:559-570 "Interleukin-1 $\beta$ induced cyclooxygenase 2 expression and prostaglandin E2 secretion by human neuroblastoma cells: implications for Alzheimer's disease"	
	AX	Horwitz and Fisher (2001) <i>New Engl. J. Med.</i> 344:1846-1850 "The Irritable Bowel Syndrome"	
	AY	Hurst, <i>et al.</i> (2002) <i>J. Immunol.</i> 169:443-453 "New IL-17 Family Members Promote Th1 or Th2 Responses in the Lung: In Vivo Function of the Novel Cytokine IL-25"	
	AZ	Ilzecka, <i>et al.</i> (2002) <i>Cytokine</i> 20:239-243 "Transforming Growth Factor-Beta 1 (TGF-BETA 1) in Patients with Amyotrophic Lateral Sclerosis"	
	BA	Ito, <i>et al.</i> (2002) <i>J Gastroenterol.</i> 37 Suppl. 14:56-61. "Anti-IL-6 receptor monoclonal antibody inhibits leukocyte recruitment and promotes T-cell apoptosis in a murine model of Crohn's disease"	

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Sheet	4	of	6	Attorney Docket Number	DX06023US01

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	BB	Kostulas, <i>et al.</i> (1999) <i>Stroke</i> 30:2174-2179 "Increased IL-1 $\beta$ , IL-8, and IL-17 mRNA Expression in Blood Mononuclear Cells Observed in a Prospective Ischemic Stroke Study"	
	BC	Levy (1996) <i>New Engl. J. Med.</i> 335:1124-1132 "Pharmacologic Treatment of Cancer Pain"	
	BD	Li, <i>et al.</i> (2001) <i>J. Neuroimmunol.</i> 116:5-14 "IL-17 and IFN- $\gamma$ mRNA expression is increased in the brain and systemically after permanent middle cerebral artery occlusion in the rat"	
	BE	Lindenlaub and Sommer (2003) <i>Acta Neuropathol. (Berl.)</i> 105:593-602 "Cytokines in sural nerve biopsies from inflammatory and non-inflammatory neuropathies"	
	BF	Lock, <i>et al.</i> (2002) <i>Nature Med.</i> 8:500-508 "Gene-microarray analysis of multiple sclerosis lesions yields new targets validated in autoimmune encephalomyelitis"	
	BG	Matthys, <i>et al.</i> (2000) <i>J. Leukocyte Biology</i> 68:447-454 "The protective effect of IFN- $\gamma$ in experimental autoimmune diseases: a central role of mycobacterial adjuvant-induced myelopoiesis"	
	BH	Matthys, <i>et al.</i> (2001) <i>Trends Immunol.</i> 22:367-371 "Mac-1+ myelopoiesis induced by CFA: a clue to the paradoxical effects of IFN- $\gamma$ in autoimmune disease models"	
	BI	Matusevicius, <i>et al.</i> (1999) <i>Multiple Sclerosis</i> 5:101-104 "Interleukin-17 mRNA expression in blood and CSF mononuclear cells is augmented in multiple sclerosis"	
	BJ	McManus and Kelleher (2003) <i>New Engl. J. Med.</i> 348:2573-2574 "Celiac Disease – The Villain Unmasked?"	
	BK	Neurath, <i>et al.</i> (1995) <i>J. Exp. Med.</i> 182:1281-1290 "Antibodies to Interleukin 12 Abrogate Established Experimental Colitis in Mice"	

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	BL	Nielsen, <i>et al.</i> (2003) <i>Scand. J. Gastroenterol.</i> 38:180-185 "Upregulation of Interleukin-12 and -17 in Active Inflammatory Bowel Disease"	
	BM	Oppmann, <i>et al.</i> (2000) <i>Immunity</i> 13:715-725 "Novel p19 Protein Engages IL-12p40 to Form a Cytokine, IL-23, with Biological Activities Similar as Well as Distinct from IL-12"	
	BN	Parham, <i>et al.</i> (2002) <i>J Immunol</i> 168:5699-708 "A Receptor for the Heterodimeric Cytokine IL-23 Is Composed of IL-12R $\beta$ 1 and a Novel Cytokine Receptor Subunit, IL-23R"	
	BO	Podolsky (2002) <i>New Engl. J. Med.</i> 347:417-429 "Inflammatory Bowel Disease"	
	BP	Rutkowski and DeLeo (2002) <i>Drug News Perspect.</i> 15:626-632 "Future directions in CNS cytokine modulation and the role of nonneuronal cells in stimuli that produce heightened sensitivity will elucidate new avenues of paid management and prevention"	
	BQ	Sedgwick, <i>et al.</i> (1991) <i>Proc. Natl. Acad. Sci. U S A</i> 88:7438-7442 "Isolation and direct characterization of resident microglial cells from the normal and inflamed central nervous system"	
	BR	Shin, <i>et al.</i> (1999) <i>Cytokine</i> 11:257-266 "Expression of IL-17 in Human Memory CD45RO <sup>+</sup> T Lymphocytes and its Regulation by Protein Kinase a Pathway"	
	BS	Sommer (2003) <i>Curr. Opin. Neurol.</i> 16:623-628 "Painful neuropathies"	
	BT	Starnes, <i>et al.</i> (2001) <i>J. Immunol.</i> 167:4137-4140 "IL-17F, a Novel Cytokine Selectively Expressed in Activated T Cells and Monocytes, Regulates Angiogenesis and Endothelial Cell Cytokine Production"	
	BU	Vrinten, <i>et al.</i> (2001) <i>Euro. J. Pharmacol.</i> 429:61-69 "Neuropathic pain: a possible role for the melanocortin system?"	

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				Attorney Docket Number	DX06023US01
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Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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